Appln. No.: 10/018,672

Amendment Dated November 10, 2008 Reply to Office Action of July 8, 2008

Remarks/Arguments:

This response accompanies a request for continued examination. The claims pending as of the July 8, 2008 Final Office Action were 55-63 and 68-74. This amendment cancels claims 56, 60, and 69-72 without prejudice, amends claims 55, 58, and 61, and adds new claims 75-84. Upon entry of this amendment, claims 55, 57-59, 61-63, 68, and 73-84 will be pending in the application. Support for the amendments to claims 55, 58, and 61 may be found throughout the application, for example, at page 5 lines 13-24, page 6 lines 13-15 and page 31 line 21 – page 32 line 2. Support for new claims 75-84 may be found throughout the specification, for example, at page 31 line 10 – page 32 line 2, page 36 lines 18-20 and page 39 line 13-15.

Claims 55, 57, 59, 62, 63, 73, 74, 77, and 78 relate to full length SEQ ID NO:2, fusion proteins comprising the full length SEQ ID NO:2, and immunogenic compositions comprising the full length SEQ ID NO:2. Claims 58, 61, 75, 76, and 79-84 relate to polypeptide fragments, fusion proteins comprising polypeptide fragments, and immunogenic compositions comprising polypeptide fragments. Claim 68 relates to a method for inducing an antibody.

Maintained Rejections - 35 USC 112, 1st paragraph

Claims 55, 58-63, 68, 70 and 72-74 were rejected under 35 U.S.C. § 112, first paragraph, for the same reasons as set forth in the previous office action. The previous office action of December 13, 2007, rejected claims 55, 58, 59, 61-63, 64-67 and 68 for lack of enablement and claims 55, 58, 59, 61, 62, 63-64, 66, 67 and 68 for lack of written description (a new matter rejection). Applicant respectfully traverses this rejection.

Enablement

Applicant respectfully submits that the enablement rejection is based on an inaccurate claim construction. The enablement rejection misconstrues the claims where it equates fragments to variants (December 13, 2007 Office Action, page 2), and where it states that the claims are "drawn to variants ... with undefined alterations" (December 13, 2007 Office Action,

Appln. No.: 10/018,672

Amendment Dated November 10, 2008 Reply to Office Action of July 8, 2008

page 3). This construction is inconsistent with the definition of the terms "fragment" and "variant" provided in the specification.

"Fragment" is defined on page 5, lines 26-27 of the specification, as "a polypeptide having an amino acid sequence that is *entirely the same* as part but not all of any amino acid sequence of any polypeptide of the invention." (Emphasis added). Examples of fragments are provided on page 5 line 27 - page 6 lines 17.

Furthermore, an immunogenic fragment of a BASB111 polypeptide is defined and exemplified on page 5, lines 13-20, as "a contiguous portion of the BASB111 polypeptide which has the same or substantially the same immunogenic activity as the polypeptide comprising the amino acid sequence of SEQ ID NO:2;... may include, for example, the BASB111 polypeptide lacking an N-terminal leader sequence, and/or a transmembrane domain and/or a C-terminal anchor domain...".

"Variant" is defined on page 49, lines 21–29 of the specification as "a polynucleotide or polypeptide that differs from a reference polynucleotide or polypeptide, but retains essential properties . . . A typical variant of a polypeptide differs in amino acid sequence from another, reference polypeptide." Examples of variants appear at page 49, line 29 to page 50, line 7.

Applicant's specification clearly states that fragments have sequences that are entirely the same as a part of a larger sequence, but variants differ from a reference sequence. Applicant's usage of the terms in the noted examples supports that distinction. The Office may not impose its own, contradictory definitions. *See, e.g.,* M.P.E.P. § 2111.01 ("Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim", *citing Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999)). Therefore the claims directed to fragments, specifically immunogenic fragments, should not be construed to claim variants as stated in the rejection, and applicant expressly requests that this rejection be withdrawn.

Written Description

The written description rejection as maintained is improper as the limitation cited in the previous office action as a basis for the rejection, "an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids having an aligned contiguous segment from

Appln. No.: 10/018,672 GSKB-120US

Amendment Dated November 10, 2008 Reply to Office Action of July 8, 2008

amino acid positions 1-47 or amino acid positions 104-276 of SEQ ID NO:2," is not present in the claims presented on March 31, 2008. Applicant respectfully requests withdrawal of this rejection.

Appln. No.: 10/018,672

Amendment Dated November 10, 2008 Reply to Office Action of July 8, 2008

New Rejections - 35 USC 112, 1st paragraph

The Final Action rejected claims 55, 58-63, 68, 70, and 72-74 under 35 U.S.C. §112, first paragraph, for allegedly reciting new matter in the limitation "57 contiguous amino acids." It is respectfully submitted that this rejection is moot in view of the amendments. Applicant respectfully request withdrawal of this objection.

Claim Objections

In the Final Action, claims 56, 57, 69, and 71 were objected to as depending from a rejected base claim. It is respectfully submitted that this objection is moot in view of the amendments to the claims. Applicant respectfully requests that this objection be withdrawn.

Respectfully submitted,

Glenn E. J. Murphy, Reg. No. 33,539 Brian A. Cocca, Ph.D., Reg. No. 58,583

Attorneys for Applicant

GEM/BAC/img/ap

Dated: November 10, 2008

✓ P.O. Box 980Valley Forge, PA 19482(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. 18-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith.

I hereby certify that the correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patent P.O. Box 1450, Alexandria, VA 22313-1450

November 10, 2008

312251_1

Anne Pinto